IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHILIP MORRIS USA INC. et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION et al., Defendants.	Civil Action No. 1:15-cv-1590 Oral Argument Requested

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Civil Rule 7(h), Plaintiffs Philip Morris USA Inc., U.S. Smokeless Tobacco Company LLC, R.J. Reynolds Tobacco Company, American Snuff Company, LLC, Santa Fe Natural Tobacco Company, Inc., and ITG Brands LLC (collectively "Plaintiffs") move the Court to enter summary judgment in their favor on all claims. As set forth in the accompanying Memorandum of Law in Support of Plaintiffs' Motion for Summary Judgment, the directive issued by the Food and Drug Administration entitled Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2) is inconsistent with the Family Smoking Prevention and Tobacco Control Act, violates the substantive and procedural requirements of the Administrative Procedure Act, infringes Plaintiffs' First Amendment rights, and is unconstitutionally vague. Accordingly, Plaintiffs are entitled to judgment as a matter of law.

Pursuant to Local Rule 7(f), Plaintiffs respectfully request oral argument on this motion.

Dated: October 30, 2015

Respectfully Submitted,

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MEMORANDUM OF LAW IN SUPPORT OF
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INTRODUCTION

Under the guise of a "guidance" document, the Food and Drug Administration ("FDA") has dramatically expanded its regulatory power beyond the bounds authorized by Congress and permitted by the U.S. Constitution. In its pursuit of pre-authorization authority over changes to tobacco product labels and the quantities in which tobacco products are packaged, FDA has upended the structure and rewritten the text of the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), jettisoned longstanding principles of reasoned agency decision-making, and imposed an unlawful prior restraint on Plaintiffs' First Amendment right to communicate with adult tobacco consumers.

This is not FDA's first attempt to assert such authority. In March 2015, FDA issued a similar "guidance" document. Even though the "guidance" was purportedly nonbinding, FDA issued an Interim *Enforcement* Policy in which the agency agreed not to enforce the document's regulatory requirements soon after Plaintiffs filed suit challenging the "guidance" in this Court. FDA re-imposed the same regulatory requirements—supported by additional, but equally flawed, statutory arguments—in its recently issued Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2) (Sept. 8, 2015) ("Second SE Directive"). Notwithstanding its innocuous title, the Second SE Directive has immediate, concrete, and far-reaching consequences for tobacco product manufacturers seeking to make label or quantity changes to their products. For multiple reasons, this Court should set aside the Second SE Directive.

First, the label-change requirements of the Second SE Directive contravene the structure and text of the Tobacco Control Act. In the Act, Congress granted FDA authority to review and approve changes to *tobacco products* before those changes are implemented, but withheld that same authority over tobacco product *labels*, with two narrow exceptions. Although those

exceptions indisputably do not apply here, FDA has claimed for itself in the Second SE Directive the power to undertake mandatory premarket review of tobacco product label changes. That regulatory power grab disregards the statutorily imposed distinction between the agency's authority to regulate tobacco products and its authority to regulate the labels that accompany those products. According to FDA, it is nevertheless empowered to impose premarket review requirements on tobacco product label changes because, "if a product's label is modified in any way that renders the product distinct from the predicate," the relabeled product is supposedly a "new tobacco product" under the Tobacco Control Act. Second SE Directive at 5 (AR007). But FDA has already conceded that a label is not a "part" of a tobacco product—a concession that conclusively establishes that a change to a tobacco product's label does not change the tobacco product itself and thus does not create a "new tobacco product" within the meaning of the Act.

Second, the label-change requirements of the Second SE Directive violate both the substantive and procedural requirements of the Administrative Procedure Act ("APA"). Substantively, the label-change requirements are arbitrary and capricious because FDA failed to articulate a reasoned basis for its decision to impose premarket review requirements on tobacco product labels, did not consider reasonable alternatives to its pre-authorization framework, departed from its prior interpretations of the Tobacco Control Act without explanation, and neglected to provide manufacturers with meaningful direction about the types of label changes that create "distinct" tobacco products subject to premarket review. Procedurally, the Second SE Directive is invalid because it is a binding, substantive rule that FDA promulgated without using the notice-and-comment procedures mandated by both the APA and Tobacco Control Act.

Third, the Second SE Directive violates the First Amendment rights of tobacco product manufacturers. The Directive's premarket review requirements for label changes impose a prior

restraint on manufacturers' speech without any of the requisite safeguards, including a deadline for FDA to complete its review and a set of narrow, objective, and definite criteria to guide FDA's decision-making. In addition, the Second SE Directive violates the well-established First Amendment protections for commercial speech because, among other reasons, FDA failed to establish that its premarket review requirements for label changes would materially advance, and are the least restrictive means of furthering, its supposed regulatory interest in "keep[ing] abreast of products in marketplace." Second SE Directive at 9 (AR011).

Fourth, the label-change requirements of the Second SE Directive are unconstitutionally vague because FDA has failed to articulate a clear standard for when premarket review of label changes is required. The Directive states only that premarket review is required where the label change is sufficient to render a tobacco product "distinct" from its predecessor, leaving manufacturers to speculate whether FDA will deem a proposed label change significant enough to implicate the Directive's requirements. Manufacturers that guess incorrectly are potentially subject to substantial civil and criminal penalties.

Finally, the Second SE Directive's product-quantity change requirements contravene the text of the Tobacco Control Act and violate the APA for many of the same reasons as the label-change requirements, including the absence of any textual support in the Act and FDA's failure to utilize the notice-and-comment procedures mandated by the APA.

For each of these reasons, the Court should enter summary judgment for Plaintiffs and vacate the Second SE Directive.

STATEMENT OF FACTS

I. Statutory Background

The Tobacco Control Act ("TCA"), enacted in 2009, added a new chapter to the Federal Food, Drug, and Cosmetic Act ("FDCA") that establishes a comprehensive framework to

regulate the manufacturing, marketing, and sale of "tobacco products," including "new tobacco products." Pub. L. No. 111-31. Through the Act, Congress sought to reduce the use of tobacco products by minors and to ensure that consumers are fully informed about the health risks of tobacco. TCA § 3(6), (7). At the same time, the Tobacco Control Act expressly prohibits the Secretary from banning the sale of tobacco products and thereby ensures the continued availability of those products to adult consumers. 21 U.S.C. § 387g(d)(3).

A central feature of the Tobacco Control Act is its requirement that "new tobacco products" undergo a premarket review procedure similar to FDA's processes for reviewing new drugs and medical devices. TCA § 910. The Act defines a "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." *Id.* § 101(a). In turn, the Act defines a "new tobacco product" as:

> (A) any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007; or
>
> (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Id. § 910(a)(1). Before bringing a "new tobacco product" to market, manufacturers must submit the product for one of two types of FDA premarket review: premarket authorization or substantial equivalence review.[1]

To reach the market through the premarket authorization procedure, a manufacturer must submit an application that includes, among other things, reports of any investigations regarding

[1] The Tobacco Control Act provides an exemption from FDA premarket review, pursuant to regulations issued under the Act, for tobacco products with certain minor changes in tobacco additives. TCA §§ 905(j)(3), 910(a)(2)(A)(ii).

the specific health risks of the new tobacco product, a "full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product," and a "full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of," the tobacco product. TCA § 910(b)(1)(A)-(C). No tobacco product has yet been the subject of a premarket authorization order.

To reach the market through the substantial equivalence procedure, a manufacturer must submit a report demonstrating that the new tobacco product is "substantially equivalent" to a predicate tobacco product that was marketed as of February 15, 2007. TCA §§ 905(j)(1)(A)(i), 910(a)(2)(A)(i). A new tobacco product is "substantially equivalent" if it "has the same characteristics as the predicate tobacco product," or if it has "different characteristics and the information submitted . . . demonstrates that . . . the product does not raise different questions of public health." *Id.* § 910(a)(3)(A). The "[c]haracteristics" of a tobacco product are its "materials, ingredients, design, composition, heating source, [and] other features." *Id.* § 910(a)(3)(B).

The Tobacco Control Act exempts from either type of premarket review so-called "grandfathered" tobacco products that were "commercially marketed in the United States as of February 15, 2007." TCA § 910(a)(1)(A). The Act also separately addresses new tobacco products that were introduced into the marketplace after February 15, 2007, but before March 22, 2011 (21 months after enactment of the Act). TCA § 910(a)(2)(B). Manufacturers may market these products—which FDA refers to as "provisional" products—without a premarket authorization order or a substantial equivalence determination if the manufacturer submitted a substantial equivalence report before March 22, 2011. *Id.* The product may remain on the

market unless and until FDA determines that it is not substantially equivalent to a predicate product. *Id.*

If a "new tobacco product . . . does not comply with the premarket requirements" of the Tobacco Control Act, FDA considers the product to be both "misbranded" and "adulterated," Second SE Directive at 2 (AR004); *see also* TCA §§ 903(a)(6), 902(6)(A), exposing the manufacturer to substantial civil and criminal penalties, *see* 21 U.S.C. §§ 331-33. Penalties include criminal fines, product seizures, injunctions against marketing the product, and civil monetary penalties. 21 U.S.C. §§ 331-334; 21 C.F.R. § 17.2.

Unlike with changes to a tobacco product's physical characteristics, the Tobacco Control Act generally does not require or authorize FDA premarket review for changes to a tobacco product's label. *See* 21 U.S.C. § 321(k) (defining "label" under the FDCA as "a display of written, printed, or graphic matter upon the immediate container of any article"). While manufacturers must submit semi-annual reports under the Act that disclose material changes to product labels implemented in the preceding six-month period, TCA § 905(i)(1)(B), (3)(D), there is no generally applicable pre-approval requirement for modifications to product labels. FDA is authorized, however, to impose regulatory sanctions and pursue civil and criminal remedies if it finds that a particular change has rendered a label false, misleading, or otherwise unlawful. *See id.* § 903(a).

There are only two narrow circumstances in which the Tobacco Control Act requires manufacturers to obtain FDA approval before implementing a label change: (1) where the label makes a "modified risk" claim that the product presents reduced health risks, and (2) where FDA has promulgated a regulation through notice-and-comment rulemaking that requires pre-approval of the label change to ensure compliance with the Act.

With respect to the first category, the Tobacco Control Act defines "modified risk tobacco products" to include, for example, products labeled with descriptors such as "'light,' 'mild,' or 'low,'" TCA § 911(b), and requires manufacturers to obtain FDA pre-approval before commercially marketing these products, *id.* § 910(a). In support of this pre-approval requirement, Congress made specific findings aimed at addressing the First Amendment standards applicable to restrictions on commercial speech. In particular, Congress asserted a "compelling government interest" in ensuring the completeness and accuracy of statements about "modified risk tobacco products," *id.* § 2(40), and likewise asserted that requiring FDA pre-approval was the "only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products," *id.* § 2(43).

With respect to the second category, Section 903 of the Act—which addresses "misbranded" tobacco products—authorizes FDA to require the pre-approval of tobacco product labels, but provides some procedural protection by mandating that FDA proceed through notice-and-comment rulemaking. In relevant part, the provision provides:

> The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate the misbranding provisions of subsection (a) and that such statements comply with other provisions of the Family Smoking Prevention and Tobacco Control Act (including the amendments made by such Act).

TCA § 903(b).

II. The 2011 "Draft Guidance"

In September 2011, FDA proposed a new policy regarding tobacco product label changes. In a "draft guidance" document, FDA declared that a label change creates a "new tobacco product" under Section 910(a)(1)(B) of the Tobacco Control Act because a product label "is considered a 'part' of that product." Draft Guidance for Industry and FDA Staff: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently

Asked Questions, at 3 (Sept. 2011) ("Draft Directive"), Compl. Ex. C (AR087). According to FDA's Draft Directive, a change to the label of a tobacco product would be subject to the same premarket review requirements as a change to the product's ingredients or other physical features. *See id.* at 2-3 (AR086-87). FDA stated, however, that where the label change was limited "to font size, ink color, or background color . . . , then [it] d[id] not intend to enforce the premarket requirements . . . , provided the modification d[id] not raise different questions of public health." *Id.* at 5 (AR089).

In response to the Draft Directive, Philip Morris USA Inc. ("PM USA") and U.S. Smokeless Tobacco Company LLC ("USSTC") submitted extensive comments demonstrating that FDA's assertion of premarket review authority over tobacco product label changes was inconsistent with the structure and text of the Tobacco Control Act, violated the First Amendment, and was otherwise unlawful. *See* Altria Client Services Comments on Draft Guidance (Nov. 8, 2011), Compl. Ex. D (AR164-78). In particular, the comments emphasized that a label is not a "part" of a tobacco product within the meaning of the Tobacco Control Act, *id.* at 4-5 (AR167-68), that the Act provides for the pre-approval of tobacco product labels only under narrow circumstances not implicated by the Draft Directive, *id.* at 4-7 (AR167-70), and that requiring pre-approval of label changes would represent an unconstitutional prior restraint, *id.* at 8-9 (AR171-72).

III. The First SE Directive

Three and a half years later, on March 4, 2015, FDA issued a document entitled Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Mar. 4, 2015) ("First SE Directive"), Compl. Ex. A (AR061-82). At the outset, FDA acknowledged that its prior interpretation of the Tobacco Control Act had been incorrect: "After reviewing the comments and information submitted in response to the

September 2011 draft guidance," FDA had "carefully reconsidered this policy" and "concluded that a label is not a 'part' of the tobacco product." First SE Directive at 3 (AR065). Persisting in its pursuit of new regulatory power, FDA nevertheless offered up another theory in an attempt to justify premarket review of tobacco product label changes.

The First SE Directive, like the Draft Directive, relied on the definition of "new tobacco product" in Section 910(a)(1). But, unlike the Draft Directive—which deemed the label to be a "part" of the "tobacco product" under Section 910(a)(1)(B)—the First SE Directive relied on Section 910(a)(1)(A), asserting:

> [I]f a product's label is modified in any way that renders the product distinct from the predicate, even if its characteristics remain the same, the modified product is a new product under section 910(a)(1)(A) of the [FDCA] because that product was not commercially marketed in the United States as of February 15, 2007.

First SE Directive at 3 (AR065). Under FDA's reasoning, a "tobacco product" with characteristics identical to one commercially marketed as of February 15, 2007, but bearing a different label, could be a "new tobacco product" because the product with the modified label "was not commercially marketed in the United States as of February 15, 2007."

Without explanation, FDA abandoned in the First SE Directive its intent generally "not . . . to enforce the premarket requirements" with respect to changes to a label's font and color. Draft Directive at 5 (AR089). It nevertheless failed to provide meaningful direction regarding the types of label changes that render a product "distinct" from the previously labeled product and thus subject to premarket review. FDA wrote:

> Whether a product with a label change results in a distinct product *depends on the circumstances*. Some types of changes that might result in a distinct product are changes to logo, identifiable patterns of color, product descriptors, or any combination thereof. One consideration would be whether the label change would lead consumers to believe that the product is different from the predicate. Therefore, when a company changes the label of a tobacco product, *FDA believes it is a new product if consumers are likely to perceive it as "new" by virtue of the different label*.

First SE Directive at 4 (AR066) (emphases added). FDA purported to illustrate the types of label changes that could render a product "distinct" by offering a series of unilluminating hypotheticals. *See, e.g.*, *id.* (changing the background color of a tobacco product's label from green to red "may result in a distinct product" but changing from white to cream "may not").

To implement FDA's newly declared premarket review authority over label changes, the First SE Directive established new pre-authorization procedures specifically for label changes. Like significant changes to a product's physical characteristics that produce a "new tobacco product," changes to a product's label that create a "new tobacco product" were required to undergo either premarket authorization or substantial equivalence review. Instead of submitting a standard substantial equivalence report, however, the First SE Directive required manufacturers to submit a so-called "Same Characteristics SE Report"—a report found nowhere in the Tobacco Control Act itself—for a tobacco product that had a modified label but the same characteristics as a product that was already on the market. First SE Directive at 4 (AR066).

In addition to unveiling a new pre-approval regime for label changes, the First SE Directive also announced—for the first time—that a change to the quantity in which a tobacco product is packaged renders the product a "new tobacco product" subject to premarket review. First SE Directive at 9-10 (AR071-72). FDA claimed that, "even if the per weight composition of additives, ingredients, and other features remains the same," a change to the product quantity in a package (for example "24 cigarettes per pack instead of 20") "renders it a new product . . . because the characteristics (e.g., amounts of ingredients) have changed." *Id.* (footnote omitted). As it did for label changes, the First SE Directive created a new reporting requirement, the "Product Quantity Change SE Report," for "new tobacco products" that are different from their predecessors only in terms of the quantity in which they are packaged. *Id.* at 10 n.14 (AR072).

IV. Plaintiffs' Prior Lawsuit And FDA's Interim Enforcement Policy

In April 2015, Plaintiffs sued FDA in this Court, challenging the First SE Directive on statutory and constitutional grounds. *See* Compl., *Philip Morris USA Inc. v. U.S. Food & Drug Admin.*, No. 15-cv-544-APM (D.D.C. filed Apr. 14, 2015). Plaintiffs' Complaint alleged that the First SE Directive exceeded FDA's authority under the Tobacco Control Act, violated the substantive and procedural requirements of the APA, and was unconstitutional under the First and Fifth Amendments.

Rather than respond to Plaintiffs' Complaint, FDA announced on May 29, 2015, that it would evaluate potential changes to the First SE Directive, and issued an "Interim Enforcement Policy" in which it agreed not to enforce the Directive's requirements while that review was ongoing. In particular, FDA stated that, during the interim period, it would not "issue any warning letters or take steps to initiate any judicial or administrative adversarial proceedings for marketing a new tobacco product without required premarket authorization" when the "new product" was the result of a label or product-quantity change. First SE Directive at 1 n.1 (AR040).

In light of FDA's announcement, Plaintiffs voluntarily dismissed their Complaint without prejudice on June 2, 2015.

V. The Second SE Directive

On September 8, 2015, FDA issued the Second SE Directive. The revised document does not materially modify the requirements that the First SE Directive imposed regarding changes to tobacco product labels and product quantity, but instead advances additional rationales in support of those measures.

A. Label Changes

Under the Second SE Directive, as under the First, a manufacturer proposing to modify a tobacco product label in a way that renders the product "distinct" from its predecessor must submit the product for FDA premarket review. Second SE Directive at 5 (AR007). To determine whether a label change renders a product "distinct," the Second SE Directive reiterates that FDA "intends to consider whether the label change would lead consumers to believe that the product is different from another tobacco product." *Id*. at 7-8 (AR009-10); *see also id.* ("FDA believes it is a new product if consumers are likely to perceive it as 'new' by virtue of the different label."). To illustrate these concepts, the Second SE Directive offers the same uninformative examples as the First SE Directive. *Id.* at 8 (AR010). Specifically, the Directive provides a chart of three types of possible label changes (background color, logo image, and product descriptors) with examples of changes that "*may* result in a distinct product" and examples of changes that "*may not* result in a distinct product." *Id.* (emphases added; capitalization omitted). Changing a label's background color from green to red "may result in a distinct product," while changing from white to cream "may not." *Id.* (capitalization omitted). Changing a logo image, for example from a star to a lion, "may result in a distinct product," while reducing the size of a logo image, for example from a larger lion to a smaller lion, "may not." *Id.* (capitalization omitted). Finally, adding a product descriptor like "premium tobacco" "may result in a distinct product," while adding italicization to existing product descriptors "may not." *Id.* (capitalization omitted).

Like the First SE Directive, the Second SE Directive creates an entirely new regulatory regime to implement premarket review requirements for tobacco product label changes. As an alternative to the premarket authorization and substantial equivalence procedures specified in the Tobacco Control Act itself, the Second SE Directive provides that, where a tobacco product is

"new" as a result of a label change but retains the "same characteristics" as its predecessor, the manufacturer can submit a Same Characteristics SE Report. Second SE Directive at 5 (AR007). Unlike the First SE Directive, however, the Second SE Directive attempts to articulate a rationale for requiring Same Characteristics SE Reports: They are supposedly "intended to provide FDA with information needed to conduct the premarket review" and "help[ ] FDA keep abreast of products in marketplace so that it can properly evaluate whether products are in compliance with the Act, for example whether they are legally marketed." *Id*. at 9 (AR011). Despite these supposed informational objectives, the Second SE Directive makes clear that a "manufacturer does not need to submit any product label as a part of its Same Characteristics SE Report." *Id.* at 13 (AR015).

With regard to the statutory basis for these requirements, FDA repeats its assertion that a product with a label change that renders the product "distinct" is "new" under Section 910(a)(1)(A) of the Tobacco Control Act because it "was not commercially marketed in the United States as of February 15, 2007." Second SE Directive at 5 (AR007). Apparently in response to Plaintiffs' prior lawsuit, however, FDA proposes yet-another interpretation of the Act to attempt to justify the same preordained conclusion. According to FDA, "the 'same characteristics' prong of the SE criteria"—referring to the standards in Section 910(a)(3) of the Tobacco Control Act for establishing substantial equivalence for products with the "same characteristics" and those with "different characteristics"—"describes products whose physical attributes are *identical* to those of the predicate." *Id*. at 6 (AR008) (emphasis added). Based on this flawed premise, FDA argues that, if a "new tobacco product" can result only from changes to the physical attributes of the product, then the "same characteristics" test would be superfluous. FDA therefore concludes that "Congress must have contemplated that there would

be 'new tobacco products' that were physically identical to predicate products that would be cleared for marketing under the 'same characteristics' prong. Products that carry new names or label modifications that render the product distinct, but otherwise have the same physical attributes as a predicate product, fall into this category." *Id.*

The Second SE Directive does not establish a timetable for FDA to evaluate Same Characteristics SE Reports. Manufacturers seeking to make label changes that, in FDA's view, would render a product "distinct" under the latest directive must wait indefinitely for FDA's authorization to market the product with the new label. In the exercise of FDA's "discretion," however, the Second SE Directive carves out two exceptions to enforcement of its premarket review requirement for label changes. Second SE Directive at 13 (AR015). First, for "provisional" tobacco products—products introduced between February 15, 2007, and March 22, 2011, and as to which a substantial equivalence report is currently pending before FDA—the Second SE Directive provides that, unless and until FDA finds the underlying "provisional" product not to be substantially equivalent, FDA does not intend to object to the commercial distribution of a "new tobacco product [that] is distinct from, but has the same characteristics as, a product that is subject to a 'provisional' SE Report," as long as the manufacturer submits a Same Characteristics SE Report and then waits 90 days before implementing the label change. *Id.* at 13-14 (AR015-16). Second, a manufacturer that has already changed the label of a "grandfathered" or "provisional" product currently on the market can continue marketing the product with the label change, but only if the manufacturer submitted a Same Characteristics SE Report within 30 days of issuance of the Second SE Directive—i.e., by October 8, 2015. *Id*. at 14 (AR016).

B. Product-Quantity Changes

The Second SE Directive, like the First, states that a change in the quantity in which a tobacco product is packaged renders the tobacco product "new," even if "the per weight composition of additives, ingredients, and other features remains the same." Second SE Directive at 16 (AR018) (footnote omitted). FDA maintains that "altering the quantity in the package is a modification of that product (e.g., a change in the amounts of ingredients, materials, other features) resulting in a new product under section 910(a)(1), thus requiring premarket authorization." *Id.* at 17 (AR019). As an alternative to a full premarket authorization application or traditional substantial equivalence report, the Second SE Directive provides that manufacturers can file a Product Quantity Change SE Report where a tobacco product is rendered "new" as a result of a quantity change.

A manufacturer that submits a Product Quantity Change SE Report must wait for FDA authorization before implementing its product-quantity change. As with label changes, however, FDA announced a discretionary limitation on enforcement of this requirement, declaring its intention not to take enforcement action with respect to a "provisional" tobacco product that is the subject of a quantity change as long as the manufacturer does not implement the change "until 90 days . . . after FDA's receipt of the complete Product Quantity Change SE Report." Second SE Directive at 23 (AR025). Manufacturers can continue marketing "grandfathered" or "provisional" products already on the market with a changed product quantity as long as they submitted a Product Quantity Change SE Report by October 8, 2015. *Id.*

VI. Plaintiffs' Challenge To The Second SE Directive

Plaintiffs in this case are six manufacturers of cigarettes or smokeless tobacco products regulated by FDA. Compl. ¶¶ 17-22. Plaintiffs have suffered—and will continue to suffer—concrete, irreparable harms as a result of FDA's promulgation of the Second SE Directive, which

prohibits Plaintiffs from modifying their product labels and the quantities in which their products are packaged without FDA pre-authorization. *Id.* at ¶¶ 103-09.

Like other consumer product manufacturers, Plaintiffs frequently modify the labels of their products to communicate with consumers more effectively. *See* Decl. of K.C. Crosthwaite ¶ 4; Decl. of J. Brice O'Brien ¶¶ 8-14, 16. Plaintiffs wish to continue making changes to their product labels and currently have label changes in various stages of development, from those that are ready to be introduced to those anticipated for release in the coming months. Crosthwaite Decl. ¶¶ 8-10; O'Brien Decl. ¶¶ 8-14, 16, 18. Those label changes include changes to images, colors, and text. Crosthwaite Decl. ¶¶ 8-10; O'Brien Decl. ¶¶ 9-14. The Second SE Directive prohibits Plaintiffs from implementing any of those label changes that would result in a "distinct" product until they have submitted a Same Characteristics SE Report to FDA and then waited at least 90 days for "provisional" products and an indefinite period for all other products. Under the Second SE Directive, however, Plaintiffs can only guess whether, in FDA's view, those label changes will render the products "distinct" and therefore subject to premarket review. Faced with the choice of either complying with the Directive or risking onerous civil and criminal penalties, several Plaintiffs have put planned label changes on hold in light of the Second SE Directive. Decl. of Heather Newman ¶ 7; O'Brien Decl. ¶¶ 8-14, 16-18.

Plaintiffs face similar regulatory obstacles with respect to product-quantity changes. Plaintiffs intend to make future product-quantity changes but, under the terms of the Second SE Directive, cannot do so without submitting a Product Quantity Change SE Report and waiting at least 90 days for "provisional" products and indefinitely for all other products. *See* O'Brien Decl. ¶¶ 15, 19-20 (describing a product-quantity change that American Snuff Company put on hold in light of the Second SE Directive); Newman Decl. ¶¶ 11-12.

STANDARD OF REVIEW

Summary judgment is warranted if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal," and "[t]he 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). A court must set aside agency action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). To survive review under this standard, an agency must "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). In addition, the agency must consider "alternative[s]" that are "neither frivolous nor out of bounds" and explain its rejection of those alternatives. *Chamber of Commerce of U.S. v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005).

Agency action must also be set aside if it is "in excess of statutory jurisdiction, authority, or limitations" or "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B), (C). It is an "essential function of the reviewing court . . . to guard against bureaucratic excesses by ensuring that administrative agencies remain within the bounds of their delegated authority." *Planned Parenthood Fed'n of Am., Inc. v. Heckler*, 712 F.2d 650, 655 (D.C. Cir. 1983). Courts "must adhere to [an] unambiguous expression of congressional intent" and reject an agency's interpretation where it is "in conflict with the statute's plain language." *OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808, 812, 814 (D.C. Cir. 1998). Courts likewise "do not accord [an agency] deference when its regulations create 'serious constitutional difficulties.'" *AFL-CIO v. FEC*, 333 F.3d 168, 175 (D.C. Cir. 2003).

ARGUMENT

I. THE SECOND SE DIRECTIVE EXCEEDS FDA'S AUTHORITY UNDER THE TOBACCO CONTROL ACT.

"In determining whether a challenged regulation is valid, a reviewing court must first determine if the regulation is consistent with the language of the statute." *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988). To "ascertain[ ] the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole." *Id.* In addition, it is a "cardinal principle" of statutory interpretation that "where an otherwise acceptable construction of a statute would raise serious constitutional problems," courts must "construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988) (noting that constitutional avoidance canon negates agency deference); *see also, e.g.*, *United States v. Caronia*, 703 F.3d 149, 168-69 (2d Cir. 2012) (rejecting FDA's interpretation of the FDCA because it would raise First Amendment problems). The structure of the Tobacco Control Act, and the plain language of the provisions on which FDA relies, make clear that the Second SE Directive's label-change requirements exceed FDA's statutory authority—a conclusion reinforced by the serious constitutional problems that would be created by FDA's interpretation of the Act.

A. The Label-Change Requirements Conflict With The Structure Of The Tobacco Control Act.

"[T]he meaning of statutory language, plain or not, depends on context." *Holloway v. United States*, 526 U.S. 1, 7 (1999) (internal quotation marks omitted); *see also Roberts v. Sea-Land Servs., Inc.*, 132 S. Ct. 1350, 1357 (2012). Indeed, "[i]t is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Mich. Dep't of Treas.*, 489 U.S. 803, 809 (1989).

Statutory text thus should not be read in a "hypertechnical" manner or "in isolation." *Id.* These principles apply with full force when a court reviews agency interpretations of its own statutory authority. *See, e.g.*, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000). Here, FDA's claim of authority to regulate tobacco product label changes in the Second SE Directive squarely conflicts with Congress's carefully calibrated regulatory framework.

Congress drew clear lines in the Tobacco Control Act between the regulation of a "tobacco product" and the regulation of a tobacco product's "label." *See, e.g.*, TCA § 101(a); 21 U.S.C. § 321(k). Manufacturers generally must comply with FDA's premarket review procedures before making a significant change to a "tobacco product" itself. TCA § 910(a)(2)(A). In contrast, the Tobacco Control Act grants FDA the authority to require pre-authorization of label changes in only two limited circumstances: (1) where the label makes a "modified risk" claim that the product presents a reduced risk of adverse health effects, *id.* § 911, and (2) where FDA adopts a specific pre-approval regulation through notice-and-comment rulemaking, *id.* §903(b). Otherwise, the statute provides a mechanism for FDA to review label changes semi-annually, only *after* they have been implemented. *Id.* § 905(i)(1)(B), (3)(D). The Second SE Directive's requirements for premarket review of label changes—which are not limited to "modified risk" products and were not promulgated through notice-and-comment rulemaking—do not fall within either of the narrow grants of statutory pre-authorization authority and therefore contravene the design and structure of the Tobacco Control Act. *See, e.g.*, *Int'l Alliance of Theatrical & Stage Emps. v. NLRB*, 334 F.3d 27, 34 (D.C. Cir. 2003) (rejecting agency's statutory interpretation as unreasonable due to a conflict with "the statute's structure").

FDA cannot salvage its label-change requirements based on its boilerplate assertion that the Second SE Directive sets forth "nonbinding recommendations." Second SE Directive at 1 (AR003). FDA is not simply rendering advice. It is determining "whether premarket review is *required*." *Id.* at 3 (AR005) (emphasis added). And FDA makes clear that a "new tobacco product that does not comply with the premarket requirements . . . is both misbranded and adulterated," *id.* at 2 (AR004), potentially subjecting manufacturers to serious civil and criminal penalties in FDA enforcement actions—a conclusion underscored by FDA's issuance of an Interim *Enforcement* Policy in the wake of Plaintiffs' challenge to the First SE Directive. *See Pharm. Research & Mfrs. of Am. v. HHS*, No. 14-1685, 2015 WL 5996374, at *9 (D.D.C. Oct. 14, 2015) (holding that an interpretive rule was "final agency action" because it constituted "a definitive and purely legal determination that put[ ] pharmaceutical manufacturers to the painful choice of complying with HHS's interpretation or risking the possibility of an enforcement action").

Nor can FDA credibly claim that the Second SE Directive "does not require the preapproval of the product's label" because it does not require manufacturers to "submit any product label" as part of the Same Characteristics SE Report. Second SE Directive at 13 (AR015). On its face, the Second SE Directive *prohibits* manufacturers from implementing label changes that purportedly render a product "distinct" from its predecessor without submitting a Same Characteristics SE Report. Only after the manufacturer has waited at least 90 days for "provisional" products—or indefinitely for FDA to make a substantial equivalence determination with respect to all other products—can the manufacturer implement the label change. Thus, even

though FDA does not require submission of the label itself, the regulatory requirements of the Second SE Directive are unquestionably triggered by, and a prerequisite to, label changes.[2]

B. The Label-Change Requirements Conflict With The Text Of The Tobacco Control Act.

The label-change requirements of the Second SE Directive are also impossible to reconcile with any plausible reading of the statutory text. *See Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) ("When the statutory language is plain, the sole function of the courts . . . is to enforce it according to its terms.") (internal quotation marks omitted). According to FDA, "[w]here consumers perceive a product as 'new' by virtue of a new name or a distinctly different label . . . , the product is new under section 910(a)(1)(A) of the FD&C Act because that product 'was not commercially marketed in the United States as of February 15, 2007.'" Second SE Directive at 5 (AR007). Thus, although FDA refuses to acknowledge as much, the Second SE Directive is necessarily interpreting the statutory term "tobacco product" to encompass a product's label: If a tobacco product has a "new name or a distinctly different label," then, in FDA's view, that product was not marketed prior to February 15, 2007, and is therefore a "new tobacco product" even if its physical characteristics remain unchanged.

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[2] In addition to ignoring the clear statutory demarcation between the regulation of tobacco products and their labels, the Second SE Directive also upends the statute's distinction between "new tobacco products" and "grandfathered" tobacco products. Section 910 of the Tobacco Control Act requires "new tobacco products" to undergo premarket review, TCA § 910(a)(1)-(2), but expressly exempts "grandfathered" tobacco products that were "commercially marketed in the United States as of February 15, 2007," from the requirements of premarket review. *Id.* § 910(a)(1)(A). Under the Second SE Directive, however, a "grandfathered" tobacco product commercially marketed before February 15, 2007, can be treated as a "new tobacco product" subject to premarket review even though only the label—and none of the product's physical characteristics—has changed. FDA's imposition of premarket review requirements on tobacco products that Congress decided to leave on the market without FDA review is incompatible with the regulatory balance struck by Congress.

The Tobacco Control Act and the FDCA, however, plainly distinguish between a "tobacco product," TCA § 101(a), and the "label" that accompanies a "tobacco product," 21 U.S.C. § 321(k). A "tobacco product" is defined as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." TCA § 101(a)(rr)(1). A "label," in contrast, is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). A "label" is thus distinct from the "article"—here, a tobacco product—itself.

In fact, FDA has never contended that a label is a "component," "accessory," or "characteristic" of a tobacco product within the meaning of the Tobacco Control Act. Moreover, while the Draft Directive asserted that a label is "part" of a tobacco product, FDA expressly abandoned that position in the First SE Directive, conceding that "a label is not a 'part' of the tobacco product." First SE Directive at 3 (AR065). Thus, as FDA itself implicitly recognizes, a tobacco product that was marketed before February 15, 2007, and then undergoes a label change is by definition the *identical* tobacco product because its characteristics remain unmodified. A label change—unaccompanied by a physical change to the product itself—therefore cannot create a "new tobacco product" within the meaning of Section 910(a)(1)(A) of the Tobacco Control Act. *See also* TCA § 915(b)(1) (requiring FDA to promulgate regulations that mandate "testing and reporting of tobacco product[s]" and providing that "tobacco products manufactured and sold by a single tobacco product manufacturer that are identical in all respects except the labels, packaging design, logo, trade dress, trademark, brand name, or any combination thereof, shall be considered as a single brand" for testing purposes).[3]

[3] To be sure, a tobacco product with a newly modified label might be commercially marketed in a different manner than when it had its previous label, but the definition of "new tobacco product" in Section 910(a)(1)(A) refers to *whether* a product was "commercially marketed in the United States as of February 15, 2007," not to *how* the product was marketed.

FDA's statutory interpretation also conflicts with the language creating a substantial equivalence pathway to market for new tobacco products. Under the Tobacco Control Act, a new tobacco product is "substantially equivalent" to a predicate product if the new product has the "same characteristics" as the predicate. TCA § 910(a)(3)(A). The statute further defines "characteristics" as "the materials, ingredients, design, composition, heating source, or other features of a tobacco product"—but not its label. *Id.* § 910(a)(3)(B). Accordingly, if the only change to a tobacco product is to its label, then by definition the tobacco product would satisfy substantial equivalence review because its "characteristics" would remain the same. As night follows day, a finding of substantial equivalence would be the inevitable result for every such tobacco product as long as the only change was to its label. Congress would not have authorized such an empty regulatory exercise.

In response, FDA asserts that Congress must have intended this result since it contemplated that products with the "same characteristics" would be subject to substantial equivalence review. Second SE Directive at 6 (AR008). But this argument ignores how the "same characteristics" substantial equivalence test works and its purpose. A product may be a "new tobacco product" subject to substantial equivalence review if its characteristics are not identical to any single prior product on the market. Such a product may nevertheless satisfy the "same characteristics" test if all of its characteristics are the same *as a range of predicate products*. Even though the product would not be identical to any single predicate, such a product could enter the market through the substantial equivalence pathway because it would have the "same characteristics" as the multiple predicate products. It therefore made eminent sense for

Congress to include a "same characteristics" standard for substantial equivalence, while excluding tobacco product labels from the scope of FDA's premarket review.[4]

FDA also identifies supposed "[p]arallels and similarities in the listing, reporting, and substantial equivalence provisions" to support the label-change requirements of the Second SE Directive. Second SE Directive at 7 (AR009). FDA points to the requirements that a manufacturer that changes the name of an existing tobacco product brand (1) list the product under Section 905(i) of the Tobacco Control Act as a product that it has introduced for commercial distribution and (2) report ingredients and harmful and potentially harmful constituents ("HPHC") under Sections 904(a)(1) and (a)(3) of the Act. According to FDA, those requirements indicate that "Congress contemplated that tobacco manufacturers who intended to introduce a tobacco product that was distinct from an earlier marketed product but had identical physical attributes would . . . submit an SE Report." *Id.* But the Act's product-listing requirements do not even mention changes to the names of tobacco-product brands. "[T]he obligation to update the list . . . [based on] a change in the 'brand/sub-brand or other commercial name'" was imposed by FDA "guidance," *id.* at 6 n.7 (AR008), and therefore sheds no light on congressional intent. And the fact that the Tobacco Control Act's ingredient and HPHC

[4] Reading "same" to mean "identical" conflicts with Congress's intent in enacting the Tobacco Control Act. In formulating the substantial equivalence standard, Congress incorporated the substantial equivalence provisions of the Medical Device Amendments. In particular, the Senate Report on the bill that became the Tobacco Control Act stated that the definition of "substantial equivalence" "is largely the same as in [the Medical Device Amendments] with a few modifications." S. Rep. No. 105-180, at 23-24 (1998). As FDA recognizes in the Second SE Directive, the Medical Device Amendments define the term "different technological characteristics" to cover only "significant change[s]." 21 U.S.C. § 360c(i)(1)(B); *see also* Second SE Directive at 6 n.6 (AR008). While FDA takes comfort from the absence of any similar definition of "different characteristics" in the Tobacco Control Act, the repetition of the same terms, within a regulatory structure modeled on the substantial equivalence pathway in the Medical Device Amendments, makes it "appropriate to presume that Congress intended the text to have the same meaning in both statutes." *Smith v. City of Jackson*, 544 U.S. 228, 233 (2005). Congress's use of the term "*substantial* equivalence" in both contexts further demonstrates that identicality is not required.

reporting requirements explicitly operate on a "brand/sub-brand" basis, TCA § 905(i)(1), simply underscores the absence of any brand-based regulatory obligations from the Act's premarket review requirements, which are triggered by the introduction of a "new tobacco product," a term the Act defines without reference to "brands," "sub-brands," or a product's label. *Id.* § 910(a)(1). If Congress had intended the Tobacco Control Act's premarket review requirements to apply to a new brand for a particular tobacco product that was previously sold under a predecessor brand, it would have adopted the same type of brand-based regulatory obligations that it did in the ingredient and HPHC reporting settings. Congress's silence on the issue is fatal to FDA's statutory interpretation.

II. THE SECOND SE DIRECTIVE VIOLATES THE APA BECAUSE IT IS ARBITRARY AND CAPRICIOUS AND WAS ISSUED WITHOUT NOTICE-AND-COMMENT RULEMAKING.

The Second SE Directive also violates both the substantive and procedural requirements that the APA imposes on agency decision-making.

A. The Second SE Directive Is Arbitrary And Capricious.

For multiple independent reasons, the Second SE Directive is arbitrary and capricious, and must be set aside.

1. FDA Failed To Articulate A Reasoned Explanation For Adopting The Second SE Directive's Label-Change Requirements.

The APA requires that an agency "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). The agency's explanation for its action must be "sufficient to enable [the court] to conclude that [it] was the product of reasoned decisionmaking." *Id*. at 52. Whereas the First SE Directive articulated *no* reasoning in support of its label-change requirements, FDA attempts in the Second SE Directive to muster at least some justification for

those new requirements. The reasons it offers, however, are unsupported by logic or common sense.

According to FDA, requiring manufacturers to submit Same Characteristics SE Reports before making a label change is necessary to "provide FDA with information needed to conduct the premarket review" and "help[ ] FDA keep abreast of products in marketplace so that it can properly evaluate whether products are in compliance" with the Tobacco Control Act. Second SE Directive at 9 (AR011). FDA's first rationale—the need for information to conduct its premarket review of the product with the modified label—is wholly circular and question-begging: FDA cannot rationally justify the premarket review requirements imposed by the Second SE Directive by pointing to the need for information to undertake that review. The question is whether that review—and its attendant reporting requirements—is warranted where a manufacturer intends to modify a product's label but keep the physical characteristics of the product unchanged.

Nor will a Same Characteristics SE Report "help[ ] FDA keep abreast of products in marketplace." Second SE Directive at 9 (AR011). FDA has made clear that it will not require manufacturers to submit the modified product label as part of the report and that it will not be pre-approving the label, which is the only item that purportedly renders the product "new." *See id.* at 13 (AR015). FDA has thus established an irrational process in which it will collect written information about relabeled products without actually receiving or reviewing the proposed labels themselves. There is accordingly no connection between the purported need to keep FDA updated on products in the marketplace and the label-change requirements imposed in the Second SE Directive.

In addition, FDA fails to explain why the Second SE Directive's label-change requirements are necessary in light of the existing regulatory requirements that already enable FDA to monitor changes to tobacco product labels and ensure that labels are accurate and non-misleading. In particular, the Tobacco Control Act requires manufacturers to submit semi-annual reports that disclose material changes to their product labels, TCA § 905(i)(1)(B), (i)(3)(D), and affords FDA the authority to deem a tobacco product "misbranded if its labeling is false or misleading," 21 U.S.C. § 387c(a). It is arbitrary and capricious for FDA to create a new premarket review requirement for label changes without establishing that the existing, congressionally mandated regulatory requirements are insufficient to serve the agency's stated goals. *See Defenders of Wildlife v. Salazar*, 842 F. Supp. 2d 181, 185-87 (D.D.C. 2012) (invalidating new agency procedures where existing procedures were working effectively and there was no evidence to support the agency's purported need for the new procedures).

2. FDA Failed To Consider Reasonable Alternatives To The Second SE Directive's Label-Change Requirements.

The Second SE Directive is also arbitrary and capricious because FDA failed to consider "reasonably obvious alternative[s]" to its needlessly burdensome regulatory approach. *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 797 (D.C. Cir. 1984) (internal quotation marks omitted); *see also Chamber of Commerce of U.S. v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005) (agencies are required to consider "alternative[s]" that are "neither frivolous nor out of bounds").

There are several reasonable approaches that FDA could have adopted to achieve its regulatory goals without requiring manufacturers to wait at least 90 days—and, for many products, indefinitely—before implementing a label change. For example, instead of imposing premarket review requirements on relabeled tobacco products, FDA could potentially have required manufacturers to notify the agency of label changes as soon as they have been

implemented. That alternative would have enabled FDA to achieve its purported objective of "keep[ing] abreast of products in marketplace"—and to take appropriate enforcement measures to address misbranded and adulterated products—without impairing manufacturers' right to introduce label changes. Second SE Directive at 9 (AR011). The Second SE Directive gives no indication that FDA considered this reasonable alternative and provides no explanation for rejecting it.

FDA's silence on possible alternatives to its premarket review requirements for label changes is especially problematic because Plaintiffs identified several feasible alternatives in comments they submitted to FDA regarding its Draft Directive and First SE Directive. *See, e.g.*, RAI Services Co. Comments on First SE Directive, at 24 (Apr. 3, 2015) (AR129) ("Rather than establish de novo premarket review requirements, FDA should promulgate regulations establishing a notification requirement only for changes to a product label . . . ."); Altria Client Services Comments on Draft Guidance, at 9 n.52 (Nov. 8, 2011) (AR172) ("manufacturers could notify FDA of name changes by updating their ingredient submissions under Section 904, or through regular product listing submissions"). Even though FDA indicated that it was taking time to "consider new comments to the guidance" when it announced its Interim Enforcement Policy in the wake of Plaintiffs' first lawsuit, *see* First SE Directive at 1 n.1 (AR040), FDA failed to respond to any of the alternatives proposed by Plaintiffs. Its failure to do so constitutes a serious departure from reasoned agency decision-making. *See City of Waukesha v. EPA*, 320 F.3d 228, 257-58 (D.C. Cir. 2003) (while an agency "need not address every comment," "it must respond in a reasoned manner to those that raise significant problems") (internal quotation marks omitted).

3. The Second SE Directive Departs From FDA's Prior Interpretations Of The Tobacco Control Act.

Although an agency is free to change positions, it must do so "by 'reasoned analysis'" in which it "acknowledge[s] and provide[s] an adequate explanation for its departure from established precedent." *Dillmon v. Nat'l Transp. Safety Bd.*, 588 F.3d 1085, 1089-90 (D.C. Cir. 2009); *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009). The Second SE Directive's unreasoned and unexplained departures from FDA's prior interpretations of the Tobacco Control Act are arbitrary and capricious.

Throughout the four-year regulatory process that culminated in the Second SE Directive, FDA has adopted inconsistent and perpetually shifting interpretations of the Tobacco Control Act in an effort to secure its predetermined objective of premarket review authority over label changes. For example, in its Draft Directive, FDA asserted that a label was "part" of a tobacco product and that a change to the label therefore created a "new tobacco product" under Section 910(a)(1)(B) of the Tobacco Control Act. Draft Directive at 2-3 (AR086-87). After receiving comments questioning that interpretation of the Act, FDA rejected that position in the First SE Directive and instead concluded that a tobacco product is "new" under Section 910(a)(1)(A) of the Act if a label change would create a "distinct" product that was not commercially marketed before February 15, 2007. First SE Directive at 3-4 (AR065-66). FDA acknowledged this change in position but failed to explain it, stating only that "[w]e have concluded that a label is not a 'part' of the tobacco product." *Id.* at 3 (AR065). That unexplained assertion hardly constitutes a reasoned explanation for FDA's fluctuating views. *See also id.* at 4 (AR066) (abandoning, without acknowledgment or explanation, the Draft Directive's policy of "not enforc[ing] the premarket requirements" regarding font and color changes that "do[ ] not raise different questions of public health").

The explanation provided in the Second SE Directive fares no better. As in the First SE Directive, FDA merely states that it "reconsidered its interpretation and concluded that a label is not 'part' of the tobacco product." Second SE Directive at 4 (AR006). FDA then exacerbates the shortcomings in that unreasoned statement by propounding yet-another new interpretation of the Tobacco Control Act that appeared nowhere in the Draft Directive or First SE Directive. In this latest approach, FDA points to "the 'same characteristics' prong of the SE criteria" as support for its position that label changes can give rise to a "new tobacco product." *Id.* at 6 (AR008); *see also supra* at 23-24 (discussing flaws in FDA's statutory interpretation). FDA does not explain why it is invoking this statutory language for the first time in the Second SE Directive. It is apparent, however, that this new analysis is merely the most recent iteration of FDA's results-oriented effort to find some statutory hook on which to premise its assertion of premarket review authority over label changes. FDA's ever-shifting readings of the Tobacco Control Act are unpersuasive on their own terms and only underscore the agency's sharp deviations from the requirements of the APA. *See Ala. Educ. Ass'n v. Chao*, 455 F.3d 386, 397 (D.C. Cir. 2006) (vacating a rule where the agency failed to provide a "reasoned analysis" of its change in position).

B. The Second SE Directive Is A Substantive Rule Promulgated Without Notice And Comment In Violation Of The APA And The Tobacco Control Act.

The power to make law cannot be exercised by anyone other than Congress, except in conjunction with the lawful exercise of executive or judicial power. Fundamental principles of administrative law, as well as FDA's own authorizing statute and regulations, thus require that the agency promulgate "legislative" or "substantive" rules through notice-and-comment rulemaking. *See* 5 U.S.C. § 553; 21 U.S.C. § 371; 21 C.F.R. § 10.40. Section 903(b) of the Tobacco Control Act likewise provides that, except with respect to "modified risk" products,

FDA can establish a pre-approval requirement for label changes only through the notice-and-comment process. *See* 21 U.S.C. § 387c(b) (permitting FDA, "*by regulation*, [to] require prior approval of statements made on the label of a tobacco product") (emphasis added); *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997) (explaining that use of the term "regulation" is "consistent only with the invocation of [FDA's] general rulemaking authority"). These procedures are essential to maintaining transparency and accountability and to ensuring that FDA acts within the limits of its delegated authority. *See, e.g.*, *Dep't of Transp. v. Ass'n of Am. R.R.*, 135 S. Ct. 1225, 1234 (2015) (Alito, J., concurring). FDA violated these requirements when it unilaterally extended its premarket review authority to tobacco product label changes through its purported "guidance," which imposes substantive requirements on manufacturers that can only be imposed, if at all, through the notice-and-comment process.

Substantive rules are agency pronouncements that "have the force and effect of law." *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000). Although the Second SE Directive is labeled nonbinding "guidance," an agency's characterizations of its own actions are not dispositive, and courts must instead determine for themselves whether the agency has promulgated a substantive rule. *See Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 34 (D.D.C. 1995). In particular, the D.C. Circuit has identified three factors to consider in evaluating whether a rule is substantive and therefore subject to notice-and-comment requirements: (1) the legal effect of the agency action on regulated entities; (2) the agency's own characterization of its action; and (3) the agency's application of its pronouncement as binding on regulated parties. *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 252-53 (D.C. Cir. 2014). FDA's invocation of the "guidance" label in this setting is facially implausible in light of its prior issuance of an Interim *Enforcement* Policy, which, standing alone, makes clear that the Second SE Directive

imposes mandatory regulatory requirements. In any event, all three factors demonstrate that the Second SE Directive is a substantive rule.

First, the Second SE Directive bears the hallmarks of a substantive rule because it "purports to impose legally binding obligations or prohibitions on regulated parties" and "would be the basis for an enforcement action for violations of those obligations or requirements." *Nat'l Mining Ass'n*, 758 F.3d at 251. On pain of substantial civil and criminal penalties, the Directive requires manufacturers to submit a Same Characteristics SE Report and then wait at least 90 days for "provisional" products, and potentially indefinitely for other products, before implementing a label change that renders the relabeled product "distinct." The Second SE Directive therefore determines the legal rights and obligations of manufacturers and requires manufacturers to take specific compliance measures. *See Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002) (deeming an EPA pronouncement to be binding because it was intended to "shape [regulated parties'] actions").

Although FDA advises regulated entities that they "can use an alternative approach if [the approach] satisfies the requirements of the applicable statutes and regulations," Second SE Directive at 1 (AR003), the Second SE Directive makes clear FDA's determination that in fact *no* alternative approach could satisfy manufacturers' regulatory obligations with respect to label changes. FDA states in the Directive that, in its view, "a change in a product label render[s] a product a 'new tobacco product' subject to the premarket review provisions of the [FDCA] . . . if a product's label is modified in any way that renders the product distinct from the predicate." *Id.* at 5 (AR007); *see also id.* at 14 (AR016) ("The tobacco product with the modified label that renders the product distinct is a new tobacco product subject to premarket requirements under section 910(a) of the FD&C Act. New tobacco products may not be sold or distributed in

interstate commerce without an order from FDA."). FDA thus stakes out the unequivocal position that, unless a manufacturer complies with the specific requirements of the premarket review procedure—through submission of a premarket authorization application or a Same Characteristics SE Report—the manufacturer will be marketing a misbranded and adulterated product. *See, e.g.*, *id.* at 2-3 (AR004-05). As a result, the only alternatives available to manufacturers are to comply with the requirements of the Second SE Directive or risk the imposition of onerous civil and criminal sanctions.

Second, the language of the Second SE Directive makes clear that it imposes binding obligations on manufacturers. As discussed above, the Directive is replete with mandatory language that requires manufacturers to take specific actions. *See, e.g.*, Second SE Directive at 14 (AR016). In addition, the binding nature of the Second SE Directive is underscored by FDA's invocation of its discretion *not to enforce* the Directive's requirements in certain limited circumstances. For example, the Second SE Directive announces that FDA "intends to exercise enforcement discretion and not take enforcement action" against products that are considered "new" under the Directive where the manufacturer of a "provisional" tobacco product submits a Same Characteristics SE Report and then waits 90 days before implementing the label change. Second SE Directive at 13-14 (AR015-16). Likewise, FDA issued an "Interim *Enforcement* Policy" after Plaintiffs filed their initial lawsuit challenging the First SE Directive, and stated that, during the interim period, it would not "issue any warning letters or take steps to initiate any judicial or administrative adversarial proceedings for marketing a new tobacco product without required premarket authorization" when the "new product" was the result of a label change. First SE Directive at 1 n.1 (AR040) (emphasis added). If the First and Second SE Directives were truly "[n]onbinding [r]ecommendations," as FDA has suggested, there would be no need for

FDA "to exercise [its] *enforcement* discretion" or adopt an interim *enforcement* policy. Second SE Directive at 13 (AR015) (emphasis added).

Third, FDA has established specific compliance deadlines based on the publication date of the Second SE Directive, which makes clear that FDA "has applied the guidance as if it were binding on regulated parties." *Nat'l Mining Ass'n*, 758 F.3d at 253. In particular, the Directive provides that manufacturers that have already made changes to tobacco product labels that rendered those products "distinct" from their predecessors can continue to market those products as long as they submitted a Same Characteristics SE Report by October 8, 2015, which was 30 days after the Directive was issued. *See* Crosthwaite Decl. ¶ 6 (explaining that PM USA submitted multiple Same Characteristics SE Reports by the October 8, 2015 deadline). The fact that FDA required manufacturers to meet this 30-day filing deadline to avoid potential sanctions for marketing misbranded and adulterated products underscores the Directive's mandatory force.

In light of the binding obligations that the Second SE Directive imposed on tobacco product manufacturers, the Directive constitutes a substantive rule that FDA was required to impose through notice-and-comment rulemaking. FDA's use of the guidance process to alter manufacturers' substantive rights and obligations with respect to the labels of their products violated both the APA and the Tobacco Control Act.[5]

III. THE SECOND SE DIRECTIVE VIOLATES THE FIRST AMENDMENT.

Product labels—and the imagery, colors, text, and brand names included on those labels—are speech protected by the First Amendment. *See, e.g.*, *Rubin v. Coors Brewing Co.*,

[5] Tellingly, in a 2011 guidance document addressing the content of substantial equivalence reports, FDA stated that it intended "to initiate a rulemaking that would establish requirements and standards for substantial equivalence under sections 905(j) and 910 of the Act." Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products, at 1 (Jan. 5, 2011) (AR462). That intent, still unfulfilled, manifests FDA's own awareness of its obligation to proceed through notice-and-comment rulemaking in this setting.

514 U.S. 476, 481-82 (1995) ("information on beer labels" constitutes protected speech).[6] Those constitutional protections apply with full force to speech regarding tobacco products because, as the Supreme Court has recognized, "so long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001); *see also R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1211-17 (D.C. Cir. 2012), *overruled in part on other grounds by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 22 (D.C. Cir. 2014) (en banc).

The Second SE Directive's label-change requirements violate the First Amendment because the Directive imposes a prior restraint that prevents manufacturers from implementing label changes—sometimes for indefinite periods of time—without establishing adequate procedural protections or concrete decision-making criteria. The Second SE Directive also imposes an unconstitutional burden on Plaintiffs' commercial speech because it restricts Plaintiffs' right to communicate with adult tobacco consumers through label changes without directly advancing a substantial government interest and in a manner that is far more extensive than necessary.

A. The Second SE Directive Imposes An Unconstitutional Prior Restraint.

A prior restraint that conditions the right to speak on pre-authorization by the government is "the most serious and the least tolerable infringement on First Amendment rights," *Neb. Press Ass'n v. Stuart*, 427 U.S. 539, 559 (1976), because "a free society prefers to punish the few who abuse rights of speech *after* they break the law [rather] than to throttle them and all others

[6] *See also Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 647 (1985) (images are protected by the First Amendment because they "serve[ ] important communicative functions"); *Friedman v. Rogers*, 440 U.S. 1, 11 (1979) ("The use of trade names . . . is a form of commercial speech.").

beforehand," *Se. Promotions Ltd. v. Conrad*, 420 U.S. 546, 559 (1975) (emphasis in original). As a result, "[a]ny system of prior restraint . . . bear[s] a heavy presumption against its constitutional validity" and can only survive constitutional scrutiny if extensive procedural and substantive protections are in place. *Id.* at 558.

The Supreme Court has established three primary procedural safeguards that are "designed to obviate the dangers of a censorship system." *Freedman v. Maryland*, 380 U.S. 51, 58 (1965). First, "the burden of instituting judicial proceedings, and of proving that the material is unprotected, must rest on the censor." *Se. Promotions*, 420 U.S. at 560; *see also Freedman*, 380 U.S. at 60. Second, "any restraint prior to judicial review can be imposed only for a specified brief period and only for the purpose of preserving the status quo" pending a final judicial determination. *Se. Promotions*, 420 U.S. at 560; *see also Freedman*, 380 U.S. at 59. This requirement is critical because "'administrative delay'" can "'become a form of censorship,'" *Heller v. New York*, 413 U.S. 483, 489 (1973), and "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury," *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion). Third, "a prompt final judicial determination must be assured." *Se. Promotions*, 420 U.S. at 560; *see also Freedman*, 380 U.S. at 59; *City of Littleton v. Z.J. Gifts D-4, L.L.C.*, 541 U.S. 774, 781 (2004) (underscoring the importance of preventing undue "*judicial*, as well as *administrative*, delay") (emphases in original). In addition to these three procedural requirements, any law that subjects "the exercise of First Amendment freedoms to [a] prior restraint . . . must contain narrow, objective, and definite standards to guide the licensing authority." *Forsyth Cnty. v. Nationalist Movement*, 505 U.S. 123, 131 (1992) (internal quotation marks omitted); *see also N.Y. Magazine v. Metro.*

Transp. Auth., 136 F.3d 123, 131 (2d Cir. 1998) ("[W]e see no reason why the requirement of procedural safeguards should be relaxed whether speech is commercial or not.").

The Second SE Directive satisfies none of these stringent prerequisites to the imposition of a prior restraint. As an initial matter, there can be no question that the Second SE Directive is a prior restraint. For non-"provisional" products, the Directive imposes an indefinite prior restraint that prevents manufacturers from changing the labels of their products in a manner that would create a "distinct" product unless and until FDA authorizes the change based on its review of the manufacturer's Same Characteristics SE Report. Second SE Directive at 4-5 (AR006-07). Past practice indicates that it could take FDA many months, or even years, to rule on a Same Characteristics SE Report—during which the manufacturer would be prohibited from freely communicating with adult tobacco consumers through the implementation of its label change. *See* U.S. Gov't Accountability Office, GAO-13-723, *New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process* 22, 39 (2013) (criticizing FDA for its delay in acting on substantial equivalence reports). And, even for "provisional" products, manufacturers must submit a Same Characteristics SE Report and are barred from implementing the labeling change for at least 90 days.

Despite imposing a prior restraint on speech, the Second SE Directive lacks the requisite procedural safeguards mandated by the First Amendment. First, FDA places the burden on the manufacturer to establish through the information provided in the Same Characteristics SE Report that the label change should be authorized—rather than shouldering the burden itself of demonstrating that the label change should not be permitted to go into effect. *Se. Promotions*, 420 U.S. at 560. Second, the Directive does not set any deadline for FDA's decision on a Same Characteristics SE Report and therefore imposes a potentially indefinite restraint on non-

"provisional" products and a restraint of at least 90 days on "provisional" products, even though prior restraints are only permissible for "preservation of the status quo for the shortest fixed period" in which the government could review the restrained speech. *Freedman*, 380 U.S. at 58; *see also Teitel Film Corp. v. Cusak*, 390 U.S. 139, 141-42 (1968) (per curiam) (invalidating a 57-day period for reviewing proposed speech). Although FDA suggests that it will make a decision regarding proposed label changes within the timeframes established by certain voluntarily adopted "performance measures," Second SE Directive at 12 (AR014), those aspirational goals—which the agency can violate at will—fall well short of the rigorous "shortest fixed period" requirement mandated by the First Amendment. *Freedman*, 380 U.S. at 58. Third, there is no guarantee that a "prompt final judicial determination" will be available to manufacturers seeking to make label changes, *Se. Promotions*, 420 U.S. at 560, because judicial review will generally not be possible until FDA has made a determination regarding a proposed label change, which itself could take many months or longer, and there is nothing in the Tobacco Control Act requiring courts to afford expedited treatment to manufacturers' legal challenges.

In addition to these procedural shortcomings, the Second SE Directive lacks any "narrow, objective, and definite standards," *Forsyth Cnty.*, 505 U.S. at 131, to guide FDA's review of proposed label changes. One of the primary "evils" condemned by the First Amendment is "a scheme" of speech regulation "that places 'unbridled discretion in the hands of a government official or agency,'" *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 225-26 (1990) (quoting *Lakewood v. Plain Dealer Publ'g Co.*, 486 U.S. 750, 757 (1988)), and that conditions the freedom of speech on "the whim of the administrator." *Forsyth Cnty.*, 505 U.S. at 133. The Second SE Directive, however, does not identify the substantive criteria that FDA will apply in reviewing label changes and does not even require FDA to articulate the basis for its decision.

That type of unchecked regulatory control of manufacturers' right to communicate with consumers—wielded by government officials unconstrained by any meaningful procedural requirements—is incompatible with the First Amendment.

B. The Second SE Directive Is An Unconstitutional Restriction On Manufacturers' Commercial Speech.

In addition to imposing an unconstitutional prior restraint, the Second SE Directive impermissibly burdens manufacturers' commercial speech rights.

Recent Supreme Court decisions suggest that to sustain a speaker-based or content-based restriction on non-misleading speech, including commercial speech, the government must satisfy strict scrutiny. *See Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226 (2015) ("Content-based laws—those that target speech based on its communicative content—are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests."). FDA, however, cannot meet even the *Central Hudson* standard, which requires the government to establish that restrictions on non-misleading commercial speech (1) further a substantial government interest, (2) directly and materially advance that interest, and (3) do so in a way that is "not more extensive than is necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980). Under this standard, FDA "bears the burden of justifying its attempt to restrict commercial speech . . . and its burden is not light." *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1218; *see also Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 548 (6th Cir. 2012) (rejecting FDA's restriction on color and graphics in tobacco advertising as "vastly overbroad" and emphasizing that government can "restrict only the speech necessary to effect its purposes").

FDA contends that Same Characteristics SE Reports "provide FDA with information needed to conduct the premarket review" and "help[ ] FDA keep abreast of products in marketplace." Second SE Directive at 9 (AR011). Even if those purported informational interests could be deemed substantial, the Second SE Directive does not directly and materially advance those asserted interests because it mandates FDA premarket review of products that have *identical* characteristics to products already on the market but that have simply been relabeled. Because the product with the new label is the *same* tobacco product as its predecessor, the Second SE Directive does not provide FDA with information necessary to fulfill its regulatory obligations under the Tobacco Control Act.

Moreover, manufacturers are already required, on a semi-annual basis, to provide FDA with copies of materially altered product labels. TCA § 905(i)(1)(B), (3)(D). The Same Characteristics SE Reports therefore provide little, if any, marginal informational benefit to the agency—especially given that manufacturers are not even required to submit the modified product labels as part of the report. *See Brown v. Entm't Merchs. Ass'n*, 131 S. Ct. 2729, 2741 n.9 (2011) ("the government does not have a compelling interest in each marginal percentage point by which its goals are advanced").

In any event, the restrictions imposed by the Second SE Directive are far broader than necessary to serve FDA's purported informational interests. As discussed above, FDA ignored several obvious alternatives that would have enabled the agency to stay apprised of label changes without burdening manufacturers' First Amendment rights. For example, FDA could simply have required manufacturers to *notify* it about label changes without mandating review before the implementation of those changes. *See supra* at 27-28. FDA's failure to evaluate less-restrictive alternatives is a fatal First Amendment flaw in the Second SE Directive. *See, e.g.*, *Thompson v.*

W. States Med. Ctr., 535 U.S. 357, 371 (2002) ("[I]f the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.").

IV. THE SECOND SE DIRECTIVE IS UNCONSTITUTIONALLY VAGUE.

To satisfy both the First Amendment's speech protections and the Fifth Amendment's Due Process Clause, laws that regulate speech "must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012). "[C]larity in regulation is essential" to ensure that regulated parties "know what is required of them" and that those enforcing the law "do not act in an arbitrary and discriminatory way." *Id.* "When speech is involved, rigorous adherence to those requirements is necessary to ensure that ambiguity does not chill protected speech." *Id.*; *see also Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 871-72 (1997) ("The vagueness of [speech regulation] raises special First Amendment concerns because of its obvious chilling effect.").

Despite requests from Plaintiffs—and FDA's own recognition that "interested parties need clarity as to [its] expectations regarding [substantial equivalence] reports," Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products, at 2 (Jan. 5, 2011) (AR463)—FDA has steadfastly refused to provide any meaningful description of the types of label changes that would render a product sufficiently "distinct" to require a Same Characteristics SE Report. Second SE Directive at 7-8 (AR009-10); *see also* RAI Services Co. Comments on First SE Directive, at 22 (AR127) ("manufacturers are left largely without any guidance to understand when their products—under FDA's new interpretation—might constitute 'new tobacco products'"). Ignoring Plaintiffs' objections without comment, the Second SE Directive offers only the inscrutable explanation that a product is "distinct" "if consumers are likely to perceive it as 'new' by virtue of the different label," as

well as a series of opaque examples of changes that "*may*"—or "may not"—"result in a distinct product." Second SE Directive at 8 (AR010). These pronouncements are cryptic to the point of being meaningless and provide wholly inadequate notice to manufacturers facing severe penalties if they guess incorrectly and fail to pursue premarket review for a label change that, in FDA's view, creates a "distinct" tobacco product.

The few examples offered in the Second SE Directive underscore the subjectivity and unworkability of FDA's "we-know-it-when-we-see-it" standard. According to FDA, changing the background color of a tobacco product's label from green to red "may result in a distinct product," but changing the background color from white to cream "may not result in a distinct product." Second SE Directive at 8 (AR010). Similarly, changing the logo image from a star to a lion "may result in a distinct product," but changing the logo from a larger star to a smaller star "may not." *Id.* These examples fail to provide manufacturers with meaningful direction and leave them to guess about whether a specific label change will trigger the Directive's premarket review requirements. For example, it remains unclear whether a change in background color from black to purple would result in a "distinct" product—or the addition of the manufacturer's web address, or an amendment to country-of-origin information.

The opacity of the Second SE Directive has had concrete consequences. For example, due to the Directive's vagueness, several Plaintiffs—including R.J. Reynolds Tobacco Company, American Snuff Company, and U.S. Smokeless Tobacco Company—have placed on hold numerous product label executions that were scheduled for 2016. O'Brien Decl. ¶¶ 8-14; *see also* Newman Decl. ¶ 7. Plaintiffs have refrained from making those changes due to the belief that FDA could conclude that some or all of the changes would create "distinct" products subject to premarket review. O'Brien Decl. ¶ 17; Newman Decl. ¶ 7. FDA's unfettered discretion under

the Second SE Directive to determine whether consumers might perceive a relabeled product to be a "new tobacco product" deprives manufacturers of the fair notice and concrete guidance that are required when constitutionally protected speech is at stake and where a failure to comply with regulatory requirements can potentially be punished with serious civil and criminal penalties.[7]

V. THE PRODUCT-QUANTITY REQUIREMENTS CONFLICT WITH THE STRUCTURE AND TEXT OF THE TOBACCO CONTROL ACT AND ARE ARBITRARY AND CAPRICIOUS.

In addition to imposing label-change requirements, the Second SE Directive provides that products will be considered "new tobacco products" subject to FDA premarket review if the quantity in which a product is packaged has changed. According to FDA, a tobacco product distributed in a new quantity is a "new tobacco product" within the meaning of the Tobacco Control Act because "the characteristics (e.g., amounts of ingredients, materials, other features, etc.) have changed." Second SE Directive at 16 (AR018). Thus, for example, when a manufacturer distributes samples of a smokeless tobacco product at a Qualified Adult Only Facility using smaller cans with a reduced quantity of the identical smokeless tobacco—as explicitly mandated by the Tobacco Control Act and FDA regulations, TCA § 102; 21 C.F.R. § 1140.16(d)(2)(iv)—the manufacturer has created a "new tobacco product" requiring FDA premarket review.

[7] FDA's failure to provide adequate direction regarding the types of label changes that will create a "new tobacco product" is also arbitrary and capricious under the APA. *See Kolender v. Lawson*, 461 U.S. 352, 357 (1983) (a regulation must allow "ordinary people" to "understand what conduct is prohibited" so that it "does not encourage arbitrary and discriminatory enforcement"); *Armstrong v. D.C. Pub. Library*, 154 F. Supp. 2d 67, 82 (D.D.C. 2001) (same). Reasoned decision-making under the APA demands far more from an agency than the promulgation of a hopelessly subjective and infinitely elastic enforcement standard supplemented by a series of unilluminating hypotheticals—particularly where the regulated industry has explicitly requested additional, concrete directions from the agency and those requests have gone unheeded. *See Pearson v. Shalala*, 164 F.3d 650, 661 (D.C. Cir. 1999) ("[I]t must be possible for the regulated class to perceive the principles which are guiding agency action."); *City of Waukesha*, 320 F.3d at 257-58.

FDA's position is flawed in numerous respects. As a threshold matter, its product-quantity requirements conflict with the plain language of the Tobacco Control Act because a tobacco product unquestionably has the same characteristics no matter the quantity of the product included in a particular package. A cigarette included in a package of 20 cigarettes has the identical "amount[ ] of ingredients, materials, [and] other features" as an identical cigarette that comes in a package of 24 cigarettes. Changing the quantity in which a product is packaged therefore does not create a "new tobacco product" with distinct characteristics from its predecessor.

The Second SE Directive's product-quantity change requirements also violate other aspects of the Tobacco Control Act. As in the label-change setting, the Second SE Directive provides that a manufacturer that makes a quantity change need not submit a full application for premarket authorization if it submits a specialized substantial equivalence report known as a Product Quantity Change SE Report. In that report—which is not contemplated anywhere in the Tobacco Control Act—FDA requires manufacturers to demonstrate that the product-quantity change is not likely to alter consumer use of the product. Second SE Directive at 21 (AR023). The Tobacco Control Act, however, explicitly requires that manufacturers submit information on the behavioral aspects of tobacco use in applications for premarket authorization and for approval of modified risk products, *see* TCA §§ 910(c), 911(g)(2), but does *not* require such information in substantial equivalence reports. That omission was purposeful and reflects Congress's intent that substantial equivalence be a more streamlined process than premarket authorization. *See Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) ("[W]here Congress includes particular language in one section of a statute but omits it in another . . . , it is generally

presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (internal quotation marks omitted).

FDA's insistence on the submission of behavioral evidence in Product Quantity Change SE Reports is particularly incongruous with respect to smokeless tobacco product samples because, as noted above, the Tobacco Control Act *requires* that any samples be distributed in smaller quantities. TCA § 102. Congress gave no indication in the statute that complying with its mandate would result in sample-size products being considered "new tobacco products" or that manufacturers would be required to support the mandatory reduction in product quantity with consumer behavioral data.

In addition, FDA's product-quantity requirements violate the substantive and procedural requirements of the APA. As with the label-change requirements, FDA has failed to consider reasonable alternatives to the imposition of its product-quantity requirements. For example, instead of requiring manufacturers to wait at least 90 days to implement a product-quantity change to a "provisional" product and indefinitely for all other products, FDA could have established a notice system that permitted manufacturers to implement quantity changes without prior approval but that required the submission of timely notice to FDA. FDA's failure to consider that and other reasonable, less burdensome alternatives was arbitrary and capricious. *See supra* at 27-28. Moreover, its imposition of these binding legal obligations through a purported "guidance" document—rather than through notice-and-comment rulemaking—violated the APA and deprived Plaintiffs and other interested parties of a full and fair opportunity to participate in the administrative process. *See supra* at 30-34.

CONCLUSION

For the foregoing reasons, the Court should enter summary judgment for Plaintiffs, declare the Second SE Directive to be unlawful, vacate it, and enjoin its enforcement.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 30th day of October, 2015, I caused the foregoing Motion For Summary Judgment and Memorandum of Law in Support of Plaintiffs' Motion for Summary Judgment to be filed and served via the Court's CM/ECF filing system.

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